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AMS MICROBIOLOGICAL DATA PROGRAM

SAMPLING RATIONALE AND PRINCIPLES

INTRODUCTION

In the past several years the number of foodborne illnesses associated with domestic and imported fresh fruits and vegetables has increased. Microorganisms once thought under control are adapting to their environments, developing resistance to conventional food processing operations. To respond to these concerns, Congress authorized an appropriation of $6.23 million for fiscal year 2001 to fund a microbiological monitoring program for foodborne pathogens on domestic and imported fruits and vegetables. This program, part of a broader (1997) Presidential Food Safety Initiative, will establish a microbiological baseline to assess the risks of contamination in the domestic food supply. The planning for this initiative is being conducted in cooperation with the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and USDA's National Agricultural Statistics Service (NASS).

CDC has expressed interest in MDP's database for developing risk assessment models based on per capita consumption for selected produce, unbiased sampling, and the systematic measurement of the frequency of contamination for specific foodborne microorganisms. FDA's interest in the program is the year-round systematic and objective sampling of highly consumed produce to complement their own program where samples taken at farmgate and packinghouses.

MDP MISSION

The purpose of MDP is to collect information regarding the incidence, number, and species of important foodborne pathogens and indicator organisms on frequently consumed domestic and imported fresh fruit and vegetables. The program, as designed, is a voluntary data gathering service and not a regulatory or enforcement effort. The data will be made available to all interested parties and published on the Internet.

The information will be collected at wholesale level and the results of analyses will be entered into a national database. As additional data from succeeding growing seasons are added, the utility of the national database will increase. The data will provide a basis for developing annual estimates and will serve as a means for measuring differences across years and different geographic production sources. Moreover, the data will provide distributional analysis of microorganisms that may indicate areas for further scientific evaluation. MDP information may have a role to evaluate the effectiveness of appropriate controls to minimize the contamination of produce to foodborne pathogens.

ADMINISTRATIVE INFRASTRUCTURE

The MDP is a voluntary program. There are more than 600 sampling sites in the 10 cooperating states. These states are California, Colorado, Florida, Maryland, Michigan, New York, Ohio, Texas, Washington, and Wisconsin. The participating states represent all regions of the country and include a little over 50 percent of the Nation's population. In addition, some of these States directly warehouse commodities supplied to distribution centers and/or supermarkets in

neighboring states, e.g., Washington to Alaska, New York to New Jersey and Western New England. The States work with USDA using cooperative agreements.

SAMPLING RATIONALE

The sampling of commodities in commerce will be conducted at wholesale markets and/or distribution centers, on a year-round, random basis and over at least two growing seasons in order to accommodate differences in growing conditions. This will permit the data to reflect differences in microbial load on the produce sample across varying conditions of production, transport, and storage. The number of samples collected by each state reflects state population. For example, California collects 14 site samples per month and commodity while Colorado and Wisconsin collect two. This provides a maximum of 62 site samples per commodity each month. Samples from a site will consist of three individual units generally collected from the same container. All samples in a state or in some cases two or more states will be collected on the same day or within a two-day interval. This creates a sufficient number of samples per set to maximize productivity with appropriate quality controls. The probability of selecting a sampling site in a state is based on produce volume. The specific algorithms were developed with NASS' assistance. This system will enable national inferences based on the data.

In developing a comprehensive and defensible baseline survey, two distinctions for each commodity are helpful to keep in mind. The first is between the individual samples of the commodity and the *target population*; that is, all units of that commodity available at the wholesale level in one of the participating states within some time range (e.g., a year). It is about the target population that assumption-free statistical statements can be made. The second distinction is between the target population and that entire amount of the commodity actually consumed by the U.S. public in the same time range, the *inferential population*. Collecting data over time from a range of sources permits vigorous statistical statements to be made about the distribution of microorganisms within the target population. The extension of statistical statements to the distribution of microorganisms within the inferential population requires us to make an assumption about the relationship between the participating States and the U.S. as a whole. We feel it is not unreasonable to assume that these states fully represent the inferential population. The participating states represent all regions of the country with significant rural-to-urban variability, reflecting that of the country as a whole.

Each sample is an individual unit of consumption. Inferences cannot reasonably be made from the sample units to the lots from which they originate, because the three sample units from a lot do not provide enough information to produce statistically reliable lot estimates. As an example, the minimum number of independent sample units needed to assure us that there is a less than 10 percent chance of not detecting at least one unit with the presence of a specific microorganism having a prevalence rate of 20 percent is 11. For a smaller prevalence rate, the minimum number of needed samples is even greater. Furthermore, at the point of sampling all or part of the entire lot may be present. Other segments may be at a different distribution site, or even reside in another state and region of the country. The product may be repacked and its identity may possibly be changed, thus the data on the origin for some of the lots may be compromised.

In general, baseline-testing programs testing product do not detain product pending analysis. In applying this principle to MDP and taking into account the time lapse which will occur from

sample receipt until a pathogen finding is verified, the product in question may no longer be available.

TESTING PROGRAM

The commodities selected for the monitoring program to begin fiscal year 2002 are tomatoes (domestic and imported), romaine and leaf lettuce, and celery. The commodities chosen for sampling are based on national consumption data in consultation with FDA and CDC. Other products to be considered for the program are cantaloupe in April 2002 and green onions/ scallions later in 2002. All commodities will be tested for the presence of Salmonella *spp.* and for generic *Escherichia coli.* In the summer of 2002, MDP plans to add *Shigella* to the testing profile. All participating states except for Maryland and Texas (sample collection only) will be involved in the laboratory-testing program.

As methodology becomes available, other organisms such as viruses or protozoa may be added to the testing profile. To support informational needs for FDA and CDC, generic *Escherichia coli* and *Salmonella* spp. isolates will be sent to an Agricultural Research Service Laboratory for antibiotic resistance examination and subsequent serotyping. This initiative is in response to an interagency work plan regarding antibiotic resistance in microorganisms on fresh produce. The Agricultural Marketing Service will provide quality assurance oversight, as well as laboratory and administrative support to the program. Standard Operating Procedures have been developed for sampling, testing, and data reporting.

STATES AND COOPERATING ORGANIZATIONS

Congressional language requested that organizations participating in baseline survey conduct the analyses blind as to source. The language is as follows: Conferees expect the Microbiological Data Program to produce national, consistent, and statistically reliable data that may be used for research and risk analysis purposes by federal agencies such as USDA, FDA, and CDC, state health departments, researchers, and other stakeholders. AMS is encouraged to contract for the data collection with organizations that have demonstrated research and technical competence, and are not barred by statute from administering a blind microbiological survey program fro fruits and vegetables. Expects AMS to hold a public within 60 days of enactment, to present a detailed data collection proposal and seek input from all interested parties."

In March 2001, AMS and FDA's Center for Food Safety and Applied Nutrition (CFSAN) agreed to procedures and timeframes for reporting data generated by laboratories participating in MDP. FDA/CSFAN requested that they receive the information quarterly. The information will be available to federal and state public health agencies and industry for food safety decision-making purposes.

CONCLUSION

Fruits and vegetables can serve as vehicles for almost any foodborne pathogenic microorganisms and result in disease under the right circumstances. The value of MDP lies in the systematic measurement of the frequency of contamination within various types of fresh produce, both domestic and imported. The data will also provide an understanding of the microbial ecology of fresh fruits and vegetables moving in the farm to table continuum, and identify trends.

Potentially, the information collected can be used to reduce the extent of contamination, if any, and thereby lower the incidence of foodborne illness.

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